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# Clinical Guidelines

## *for Office-based Surgery*

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***Prepared by***

Committee on Quality Assurance  
in Office-based Surgery  
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***Endorsed by***

New York State Public Health Council  
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New York State Department of Health  
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STATE OF NEW YORK  
DEPARTMENT OF HEALTH  
CORNING TOWER BUILDING  
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# PUBLIC HEALTH COUNCIL

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September 12, 2000

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Dear Dr. Novello:

On behalf of the Public Health Council's Committee on Quality Assurance in Office-Based Surgery, chaired by Bernard Rosof, M.D., I am pleased to present the *Clinical Guidelines for Office-Based Surgery (OBS)* and the Committee report. The Guidelines and Report are expected to promote increased patient quality and safety in office-based surgical practices.

The Committee worked diligently and intensively; members spent more than two years reviewing existing clinical guidelines, and meeting with representatives of OBS accrediting bodies, other states that have regulated OBS as well as providers, health professionals and consumers. These documents identify essential components an office-based surgical practice should address, including recommendations for anesthesia, pre- and post-surgical evaluations, monitoring equipment, credentialing, informed consent and emergency protocols.

The Public Health Council received the Committee's report in January and a Subcommittee, chaired by Dr. Cimino, reviewed the documents and recommended adoption. The Public Health Council unanimously adopted the Guidelines on July 28, 2000.

As Chair of the Public Health Council, I am pleased to deliver these comprehensive, landmark Guidelines and Committee Report to you for dissemination and future evaluation.

Sincerely,

David E. Edwards  
Chairman



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# **COMMITTEE ON QUALITY ASSURANCE IN OFFICE-BASED SURGERY**

**A Report to:**

**New York State Public Health Council  
and  
New York State Department of Health**

**July 2000**



## Statement of Purpose

The movement of health care services away from traditional inpatient facilities to outpatient settings has escalated the volume of surgery (including invasive procedures) being performed in the private offices of health care practitioners. While the vast majority of these services are provided in a safe and effective manner, the complexity of services and procedures being performed in private practitioners' offices is increasing at unprecedented levels.

While surgery performed in New York State medical facilities licensed under Article 28 of the Public Health Law (hospitals and diagnostic and treatment centers including ambulatory surgery centers) is subject to regulatory standards established under such law, surgery (including invasive procedures) performed in the private office of a physician, dentist or podiatrist is not subject to the same or similar regulatory standards, regardless of the scope or complexity of the surgical procedure.

A practitioner's authority to perform procedures in an office is established by that practitioner's license to practice his or her profession. The care delivered in such offices is expected to meet prevailing standards of care for the licensed profession. In order to provide practitioners who perform office-based surgery (OBS) with the benefit of uniform professional standards and to promote consistently high quality of care, in late 1997, the New York State Public Health Council (PHC) and the Commissioner of Health identified the increase of office-based surgery as an issue to be addressed. They jointly appointed an ad hoc Committee on Quality Assurance in Office-based Surgery to review relevant matters and develop guidelines that practitioners may use in establishing an OBS practice.

Following an 18-month deliberative process that benefited greatly from the input of the public at large and providers of care, the Committee hereby presents its report to the PHC and Department of Health (DOH) and recommends that they review and endorse these guidelines, and issue and promote the guidelines to all office-based surgical practitioners in New York State.

These guidelines are recommended as an appropriate standard for medical care which is subject to review by DOH through the Board for Professional Medical Conduct, and for dental and podiatric care, subject to review by the State Education Department (SED). The Committee and, through their support for these guidelines, the PHC and DOH, believe that surgical and anesthesia care, regardless of where performed or by whom should be provided in accordance with accepted standards of practice and in a manner that ensures the safety of the patient during the performance of surgery, administration of and recovery from anesthesia and discharge from the facility.

## Background

To ensure that the public is adequately protected when undergoing surgery/invasive procedures in private offices of health care practitioners, in late 1997 the New York State Commissioner of Health, and the PHC, agreed to establish an ad hoc Committee on Quality Assurance in Office-based Surgery. Functioning under the auspices of the PHC, the Committee, chaired by Bernard Rosof, M.D., F.A.C.P., was composed of distinguished individuals representing various surgical specialties, anesthesiology, internal medicine, dentistry, managed care plans and organizations, and consumers.

In the appointment letter to Committee members, the Commissioner made the following statement:

*“The Committee is being established at a critical time. The trend in medical care is moving the provision of services away from traditional inpatient facilities to more cost efficient and patient convenient outpatient settings. Ambulatory surgery centers, licensed under the New York State Public Health Law, have experienced continuous growth throughout the 1990s. The volume of outpatient surgical procedures also is increasing in private physician offices. This trend is likely to increase as financial disincentives are eliminated and patients are encouraged to seek less costly health care alternatives. While the vast majority of these services will be provided in a safe and effective manner, it must be recognized that the complexity of services and procedures being performed in physicians’ offices is increasing at unprecedented levels. To promote increased patient care quality and safety in office-based surgical practices, the Committee is charged with the development of guidelines that physicians may use in establishing an office-based surgery practice. The Committee will identify the components of a surgical procedure that need to be addressed, e.g., anesthesia, pre- and post-surgical evaluation, monitoring equipment, informed consent, emergency protocols, etc. It is anticipated that the Committee will develop specific guidelines/recommendations for each of these components . . . I believe the recommendations of the Committee will promote safer surgical practice in New York and will serve as a model for the rest of the nation.”*

## **Committee Process**

The Committee met regularly between December 1997 and April 1999 and held three public hearings (in New York City, Rochester and Albany) to solicit formal comment from interested parties. All meetings were open to the public and the Committee benefited greatly from the active participation of practitioners, facility representatives and representatives of health care accrediting agencies and others. SED staff also attended and provided comments.

The Committee invited formal presentations from representatives of accrediting agencies; representatives of the states of California and New Jersey, which have established programs to oversee OBS; DOH facility surveillance staff and DOH Office of Professional Medical Conduct staff; and a representative of the Commission on Office Laboratory Accreditation. In its research to learn as much as possible about the current status of OBS and generally accepted standards in this area, the Committee reviewed a wide variety of resource documents which served as the basis for many of the guidelines.

## **Supporting Efforts**

In addition to the development of recommended standards for OBS, the Committee considered a number of other matters. To gain a better understanding of the current volume and scope of OBS in New York State, the Committee initiated a survey in collaboration with the Medical Society of the State of New York (MSSNY). Questionnaires were mailed to a sample of more than 4,600 physicians to obtain information on the current practice of OBS in the state. Despite a 15 percent response rate, the survey did provide some baseline demographics for OBS practitioners, as well as data related to their specialty, procedures, anesthesia levels and emergency provisions. Forty-seven percent (329) of survey respondents indicated they currently perform OBS. The majority of OBS respondents were 46-50 years old, male,

residents of New York County and in the practice of General Surgery. In addition, 69 percent of OBS respondents ranked local anesthesia as their primary level of sedation.

Recognizing that additional data are needed, the Committee asked DOH to issue a Request for Proposal, seeking to contract with an entity to perform voluntary accreditation-type surveys of a number of office-based practices. The surveys will be done both before and after the issuance of guidelines. One goal of this project will be to collect data on how well OBS practices are currently meeting accepted standards of care. The other goal will be to measure the impact the guidelines will have on OBS practices.

## Summary/Recommendations

The guidelines contained in this document are recommended to assist OBS practitioners in providing high quality and safe care. They are recommended as an appropriate standard of care that has been endorsed by the Committee, the New York State Public Health Council and the New York State Department of Health.

In addition to issuing and endorsing these guidelines, the Committee makes the following recommendations.

- a. DOH should endeavor to gauge the effects of these guidelines on the quality of patient care in OBS practices. It should also develop a mechanism to monitor outcomes of OBS.
- b. If subsequent data indicate that these guidelines, issued as recommendations to providers, are not adequate to promote high-quality OBS services, DOH should seek statutory authority to adopt regulations that will ensure the provision of high quality care and patient safety in office-based practices.
- c. Office-based practices (especially those practices performing other than minor surgery, routine dentistry, podiatry and procedures which use unsupplemented local anesthesia) should strongly consider the use of outside accrediting agencies to help assure the public that they are providing care and services in a safe environment and adhering to the highest standards of quality and professionalism. Accreditation is also seen as a means of assisting a practitioner in meeting the guidelines. Accrediting organizations currently include the Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the American Medical Accreditation Program (AMAP). Practices should also utilize an objective method of credentialing and recredentialing each practitioner performing OBS to ensure practitioner competence and earn patient confidence.
- d. This document encourages office-based practices to establish and maintain performance improvement programs which review the activities of the practice to improve the quality of care. Data related to such activities undertaken by Article 28 facilities are protected from discovery/disclosure under New York State law. Since such protection optimizes the effectiveness of performance improvement programs, DOH should consider seeking similar legislation to protect such data collected by OBS practices from discovery/disclosure.

- e. DOH should explore whether the New York State Patient Occurrence Reporting and Tracking System (NYPORTS) now in use for hospitals can be adapted to capture data on outcomes from OBS, particularly those episodes resulting in transfers to acute care hospitals. It should also confer with practitioner specialty societies and provider associations to consider whether cooperation in a voluntary reporting program is feasible.



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**CHAPTER A****Statement of Intent and Goals**

The following are clinical guidelines for surgical or other invasive procedures performed in offices not regulated by Article 28 of the Public Health Law (hospitals, diagnostic and treatment centers and ambulatory surgery centers are covered by Article 28). These office-based surgery (OBS) guidelines have been developed after extensive research, expert input and discussion by the New York State Public Health Council's Committee on Quality Assurance in Office-based Surgery.

These guidelines are intended to provide uniform professional standards of care for practitioners who perform surgery (including invasive procedures) which require anesthesia, analgesia or sedation (and also include cryosurgery and laser surgery) in private offices. Included are recommendations for qualifications of practitioners and staff, equipment, facilities and policies and procedures for patient assessment and monitoring. Minor procedures in which unsupplemented local anesthesia is used in quantities equal to or less than the manufacturer's recommended dose, adjusted for weight, are excluded from these guidelines. Nevertheless, any practice performing OBS, regardless of anesthesia, should have the necessary equipment and personnel to be able to handle emergencies resulting from the procedure and/or anesthesia.

All medical care provided by physicians and physician assistants is subject to review by the New York State Department of Health (DOH) through the Board for Professional Medical Conduct; dental, podiatric and nursing care are subject to review by the State Education Department (SED). Both DOH and SED anticipate all surgical and anesthesia care, regardless of where provided, will be provided in accordance with accepted standards of practice and will ensure the safety of the patient during the performance of surgery, administration of and emergence from anesthesia and discharge from the care setting.

Dentists are required, by statute, to comply with the dental anesthesia law and implementing SED regulations.

While these guidelines are not statutorily based, they represent uniform professional standards of care and may help to clarify a practitioner's obligations under law and regulation.

## **CHAPTER B**

### **Definitions**

1. *Conscious Sedation (sedation analgesia)*: A minimally depressed level of consciousness that retains the patient's ability to maintain adequate cardiorespiratory function and the ability to independently and continuously maintain an open airway, a regular breathing pattern, protective reflexes and respond purposefully and rationally to tactile stimulation and verbal command. This does not include unsupplemented oral preoperative medications or nitrous oxide analgesia.

2. *General Anesthesia*: The administration of a medication(s) by the parenteral or inhalation routes which results in a controlled state of unconsciousness accompanied by a complete loss of protective reflexes including loss of ability to independently and continuously maintain patent airway and a regular breathing pattern. There is also an inability to respond purposefully to verbal command and/or tactile stimulation.

3. *Local Anesthesia*: The introduction of a local anesthetic agent into a localized part of the body by topical application or local infiltration in close proximity to a nerve, which produces a transient and reversible loss of sensation. All local anesthetics possess both excitatory (seizure) and depressant (loss of consciousness) central nervous system effects in sufficient blood levels and may have profound cardiovascular depressant effects. There may also be interactive effects between local anesthetic agents and sedative medications.

- a. *Supplemented Local Anesthesia*: The use of local anesthesia supplemented with conscious sedation;
- b. *Unsupplemented Local Anesthesia*: The use of local anesthesia without supplementing with conscious sedation.

4. *Minor Procedures*: Procedures that can be performed safely, with a minimum of discomfort, and where the likelihood of complications requiring hospitalization is minimal by current best practice experience on a patient who has received:

- a. local or topical anesthesia in quantities equal to or less than the manufacturer's recommended dose, adjusted for weight, and/or
- b. nitrous oxide analgesia, with or without oral/preoperative medication.

Minor procedures do not include tumescent liposuction or large volume liposuction. These procedures would follow the recommendations, at a minimum, in Chapter G #2, p. 11, for conscious sedation. Some literature defines large volume liposuction as removal of more than 1,500 cc of fat.\*

\*An article in the May 13, 1999, issue of the *New England Journal of Medicine* entitled "Deaths Related to Liposuction" cites an article in the November 1993 issue of *Plastic and Reconstructive Surgery* entitled "Tumescent Technique for Local Anesthesia Improves Safety in Large-Volume Liposuction" that defines large volume liposuction as removal of 1,500 cc or more of fat. The definition is based on the increased risk of blood loss when more than 1,500 cc are aspirated.

5. *Monitoring:* The continual clinical observation of a patient and the use of instruments to measure, display and record the values of certain physiologic variables such as pulse, oxygen saturation, level of consciousness, blood pressure and respiration.

6. *Office-based Surgery:* Any surgical or other invasive procedure requiring anesthesia, analgesia or sedation including cryosurgery, laser surgery and high-volume liposuction which is performed by a practitioner in a location other than a hospital (as defined in Article 28 of the NYS Public Health Law) or a diagnostic and treatment center including freestanding ambulatory surgery centers (as described in 10 NYCRR section 600.8) and which results in a patient stay of less than 24 consecutive hours.

7. *Personnel:* The practitioner(s), unlicensed personnel and any other individuals employed by or affiliated with the practice (including by contract).

8. *Practitioner:* A physician, dentist, podiatrist or other health care practitioner licensed by SED and whose professional practice is subject to review by the DOH Board for Professional Medical Conduct or the SED Office of Professional Discipline.

9. *Regional Anesthesia:* Administration of local anesthesia agents to interrupt nerve impulses in a major region of the body. Included in this category, for example, are spinal, epidural, caudal, upper or lower extremity plexus block anesthesia and intravenous regional anesthesia.

10. *Tumescent Liposuction:* Liposuction involving the subcutaneous infusion of a solution containing a local anesthetic drug, followed by the aspiration of fat through microcannulas. The infusate typically consists of 1 l of normal saline containing 500 to 1,000 mg of lidocaine, 0.25 to 1.0 mg of ephinephrine and 12.5 mml of sodium bicarbonate.

11. *Unconscious or Deep Sedation:* The administration of medication(s) by the oral, parenteral or inhalation routes which results in a controlled state of depressed consciousness accompanied by partial loss of protective reflexes. There may be an inability to independently and continuously maintain an open airway and/or regular breathing pattern with unconscious or deep sedation, and the ability to appropriately and rationally respond to physical stimuli and verbal commands is lost.

**CHAPTER C****Office Administration**

The following chapter summarizes some of the key written documents as well as the policies and procedures that OBS practices should develop and implement. The extent of this material would vary depending upon the size and complexity of the OBS practice. The policies and procedures should be reviewed and updated at least biennially. The additional chapters of these guidelines contain more detailed information and recommendations for practices (also see Appendix I, p. 21).

*1. Policies and Procedures:* Developing brief and simple written policies and procedures in the areas that follow can assist OBS practices in providing safe and high-quality surgical care, in informing patients and responding to their needs and in assuring consistent personnel performance. It is important to ensure that office personnel understand and know how to implement these procedures.

- a. **Emergency Care and Transfer Plan:** The practice should develop an emergency care plan that includes the safe and timely transfer of patients to a nearby hospital when hospitalization is indicated. The plan should be consistent with Chapter F (p. 10) of these guidelines.
- b. **Medical/Dental/Podiatric Record Maintenance and Security:** The practice should have a procedure for initiating and maintaining a health (medical/dental/podiatric) record for every individual assessed or treated. Procedures should also be in place to assure the security and confidentiality of all patient data and information. The record should include:
  - the identity of all practitioners involved in the care of the patient;
  - a procedure code or suitable narrative description of the procedure with sufficient information to identify the patient, support the diagnosis, justify the treatment and document the outcome and any required follow-up care;
  - documentation of the mode of anesthesia used, drugs and fluids administered;
  - the record of monitoring of vital signs;
  - the patient's state of consciousness during the procedure; and
  - documentation of informed consent for the procedure.
- c. **Surgical Services/Invasive Procedures:** The practice should describe the scope of surgical services/invasive procedures offered in the OBS setting, appropriate staffing and ancillary support available for the planned surgical procedures.
- d. **Maintenance of Surgical/Anesthesia Equipment:** The practice should have a procedure for regular maintenance and inspection of all surgical and anesthesia equipment and machines consistent with manufacturers' recommendations. A record of such maintenance should be retained.

- e. **Infection Control Policy:** The practice should develop and implement a procedure and a schedule for cleaning, disinfecting and sterilizing equipment and patient care items. Personnel should be trained in infection control practices and in the implementation of universal precautions. Protective clothing and equipment should be available as needed. See Chapter H, Paragraph 2 (p. 17), for additional information.
- f. **Organizational Structure/Job Descriptions:** The practice should describe its organizational structure including lines of authority, responsibilities, accountability and supervision of personnel. A written record of the job description of all personnel, including practitioners and unlicensed individuals, should be maintained. The responsibilities and supervision of any student personnel should be clearly defined and written. Educational opportunities for all personnel should be encouraged. The performance of all personnel should be continually demonstrated, assessed, maintained and improved when necessary.
- g. **Patients' Rights:** The practice should recognize the basic rights of its patients. A patients' rights document should be available to each patient. Office personnel should also be aware of and understand the importance of maintaining patients' rights. A model Office-based Surgery Patients' Bill of Rights is contained in Appendix III, (p. 26).

2. *Performance Improvement (PI) Program:* Each practice is encouraged to establish and maintain a performance improvement program which should assess both process and clinical outcomes of the practice to improve the quality of care; this should include peer review. The scope and breadth of this program should depend on the size of the practice, the level of anesthesia used and the complexity of services provided.

- a. PI can be accomplished by:
  - establishment of an internal PI program by the practice; or
  - a cooperative agreement with a hospital-based performance or quality improvement program; or
  - a cooperative agreement with another practice to jointly conduct PI activities; or
  - a cooperative agreement with a peer review organization, a managed care organization, a specialty society or other.
- b. PI activities may include but should not be limited to:
  - review of the appropriateness and necessity of procedures performed;
  - review of mortalities;
  - review of complications, and resultant outcomes including all postoperative infections;
  - review of direct patient transfers to an acute care facility;
  - review of complaints and patient satisfaction surveys;

- identification of undesirable trends, such as diagnostic errors, unacceptable results, follow-up of abnormal test results and medication errors.
- c. Findings of the PI program should be incorporated into the practice's educational staff development plan.
  - d. Practitioners should be aware that private practices, unlike hospitals and some other care providers, do not retain legal protection from discovery of information collected for PI activities. Until such time as legal protection is granted, practices should assess how best to structure PI programs within the current statutory environment.



## **CHAPTER D**

# **Credentialing**

### *1. Credentialing the Practitioner:*

- a. The specific office-based surgical/invasive procedures and anesthesia services which each practitioner is qualified and competent to perform should be commensurate with the practitioner's level of training and experience. These should be reviewed periodically and revised as necessary by the practitioner/practice.
- b. When credentialing, the following criteria should be considered:
  1. state licensure;
  2. procedure-specific education, training, experience and successful evaluation appropriate for the patient population being treated (e.g., pediatrics);
  3. for physician practitioners, board certification or completion of a training program qualified to lead to board certification; for nonphysician practitioners, certification that is appropriate and applicable for the practitioner;
  4. professional misconduct and malpractice history;
  5. participation in peer and quality review;
  6. participation in continuing education consistent with the statutory requirements and requirements of law and/or the practitioner's professional organization;
  7. malpractice insurance coverage adequate for the specialty;
  8. procedure-specific competence (and competence in the use of new procedures/technology), which should encompass education, training, experience and evaluation, and which should include the following:
    - adherence to professional society standards; and/or
    - hospital and/or ambulatory surgical privileges for the scope of services performed in the OBS setting; and/or
    - credentials approved by a nationally recognized accrediting/credentialing organization; and/or
    - didactic course complemented by hands-on, observed experience; training is to be followed by a specified number of cases supervised by a practitioner already competent in that procedure, in accordance with professional society standards and guidelines.

*2. Unlicensed Personnel:* Unlicensed personnel should not be assigned duties or responsibilities that require professional licensure. Duties that do not require professional licensure and are assigned to unlicensed personnel should be in accordance with their training, education and experience and under the direct supervision of a practitioner.

**CHAPTER E****Patient Admission and Discharge**

1. *Patient Selection:* Patients should be under the care of a licensed practitioner who should evaluate the condition of the patient and potential risks associated with treatment options. Practitioners should determine that the patient has an adequate support system to provide for necessary follow-up care. A patient who, by reason of pre-existing medical or other conditions, is at undue risk for complications, should be referred to an appropriate specialist for a preoperative consultation, and to another treatment setting and other appropriate facility for performance of the surgery and administration of the anesthesia, if warranted.

2. *Informed Consent:* Informed consent of the patient and/or, if applicable, the patient's representative, should be obtained before surgery. Informed consent should only be obtained after a discussion of risks, benefits and alternatives and should be documented in the patient's health record.

3. *Preoperative Assessments and Preanesthetic Examinations and Evaluations:*

- a. A preoperative assessment, based on medical history, an appropriate physical examination conducted within 30 days and appropriate laboratory studies should be performed by a practitioner qualified to assess the influence of relevant disease processes on surgery and anesthesia.
- b. A preanesthetic examination and evaluation should be conducted immediately prior to surgery by the physician, dentist or podiatrist who will be administering or supervising the anesthesia. If a certified registered nurse anesthetist (CRNA) is administering anesthesia, that individual should also conduct a preanesthetic examination and evaluation. Results of the examinations and evaluations should be incorporated into the health record.

4. *Discharge Evaluation:* No patient should be discharged until a qualified practitioner determines adequate recovery from anesthesia and the surgical procedure. Documentation of evaluation for discharge should be noted in the health record. Criteria for discharge for all patients who have received anesthesia should include a determination that the patient:

- a. has stable vital signs;
- b. has returned to preprocedure mental status;
- c. ambulates without dizziness;
- d. has minimal bleeding, pain, nausea and vomiting; and
- e. will be discharged in the company of a responsible adult.

5. *Patient Instruction:* Verbal instructions understandable to the patient, confirmed by written instructions (with the provision of such instructions documented in the health record), as appropriate, should be provided to each patient at discharge. The following should be included in the instructions:

- a. the name of the responsible practitioner;

- b. the procedure performed;
- c. information about complications that may arise;
- d. telephone number(s) to be used by the patient should complications or questions arise;
- e. instructions for medications prescribed, if any, and pain management, if appropriate;
- f. date, time and location of the follow-up visit or return visit; and
- g. designated place to go for treatment in the event of emergency.

**CHAPTER F****Emergency Care and Transfer Policy**

1. Appropriate emergency supplies, equipment and medications should be available and provided in accordance with the scope of surgical and anesthesia services provided at the private practitioner's office.
2. In an office where anesthesia services are to be provided to infants and children, the required emergency equipment should be appropriately sized for a pediatric population, and personnel should be appropriately trained to handle pediatric emergencies.
3. A practitioner who is qualified in resuscitative techniques and emergency care should be present and available until all patients have been discharged from the office.
4. In the event of medical complications, emergencies or other untoward events, personnel should be familiar with the procedures and the plan to be followed, and should be capable of taking necessary action. There should be a documented plan and procedure for the safe and timely transfer of patients to a nearby hospital. The plan should include arrangements for an emergency ambulance service/911 and, when appropriate, escort of the patient to the hospital by an appropriate practitioner (see Office Administration, Chapter C, paragraph 1a, p. 4). When Advanced Cardiac Life Support (ACLS) has been initiated, the plan should include a provision to immediately contact the ambulance service/911.

**CHAPTER G****Anesthesia Services***1. General Requirements:*

- a. Anesthesia should be administered only by a licensed, qualified and competent practitioner. Registered professional nurses (RNs) who administer anesthesia as part of a medical, dental or podiatric procedure (including but not limited to CRNAs) should have training and experience appropriate to the level of anesthesia administered, and function in accordance with their scope of practice. Supervision of the anesthesia component of the medical, dental or podiatric procedure should be provided by a physician, dentist or podiatrist who is physically present, who is qualified by law, regulation or hospital appointment to perform and supervise the administration of the anesthesia and who has accepted responsibility for supervision. The physician, dentist or podiatrist providing supervision should:
  1. perform a preanesthetic examination and evaluation;
  2. prescribe the anesthesia;
  3. assure that qualified practitioners participate;
  4. remain physically present during the entire perioperative period and immediately available for diagnosis, treatment and management of anesthesia-related complications or emergencies; and
  5. assure the provision of indicated postanesthesia care.
- b. Anesthesia should be administered in accordance with current standards of professional practice as described in DOH regulations for hospitals and ambulatory surgery centers (see Appendix IV, p. 28).
- c. The practitioner responsible for monitoring and, if applicable, the personnel assisting in monitoring the patient during administration of anesthesia and postanesthesia care should possess documented competency to perform such tasks.
- d. The medical, dental or podiatric record for the patient should include documentation of the mode of anesthesia used, drugs and fluid administered, the record of monitoring of vital signs and the state of consciousness during the procedure.
- e. In accordance with their legal scope of practice, podiatrists may neither administer nor supervise the administration of general anesthesia.

*2. Conscious Sedation (Sedation Analgesia) and Supplemented Local Anesthesia Administered by a Practitioner in an Office Setting:*

- a. Required expertise and experience of practitioners:

1. In order to competently administer anesthetics and/or medications that induce conscious sedation (sedation analgesia), the practitioner:
    - should be professionally qualified and experienced in delivering such agents; for parenteral conscious sedation, dentists should have dental anesthesia certification issued by SED;
    - should be available and be able to competently and proficiently use necessary monitoring and emergency equipment.
  2. The practice:
    - should have written protocols available for patient risk assessment, recovery area and emergency procedures;
    - should convene, at least annually, an in-service training on these policies and procedures.
- b. Other personnel:
1. The monitoring personnel should monitor relevant physiologic variables and be available from the time of administration of the sedative medication until recovery is judged adequate by an appropriate practitioner or the care of the patient is transferred to personnel performing recovery care. The monitoring personnel may assist with minor, interruptible tasks consistent with their licensed scope of practice or, for unlicensed personnel, consistent with the provisions stated in Credentialing, Chapter D, paragraph 2, p. 7.
  2. The minimum number of available personnel during conscious sedation should be two: the practitioner performing the surgery and the individual monitoring the patient.
  3. RNs with documented competence to administer conscious sedation (sedation analgesia) and to assist in any support or resuscitation measures, as required, should have the anesthesia component of the medical, dental or podiatric procedure supervised by a practitioner qualified for such supervision who is physically present and available to immediately diagnose and treat the patient for anesthesia complications or emergencies. (See Anesthesia Services, Chapter G, paragraph 1a, for the qualifications for supervision, p. 11.)
- c. Training for practitioners should include:
1. current Advanced Cardiac Life Support (ACLS) training and/or, if appropriate, Pediatric Advanced Life Support (PALS) or other profession-specific equivalent training; and
  2. continuing education in keeping with professional standards for maintaining quality of practice regarding proper dosages, age-related management of toxicity or hypersensitivity to anesthetic agents and medications.

- d. Equipment: Intravenous (IV) access should be maintained until the patient is fully alert. The following safety systems and monitoring devices should be immediately available when administering conscious sedation:
  1. blood pressure apparatus and stethoscope;
  2. reliable source of oxygen;
  3. a source of suction, suction catheter;
  4. appropriate size airways and masks;
  5. positive pressure ventilation device (self-inflating bag);
  6. epinephrine or other vasopressor;
  7. antihistamine to treat an anaphylactic reaction;
  8. a pulse oximeter with appropriate alarms;
  9. a continuous EKG with the capacity for a paper record;
  10. a cardiac defibrillator;
  11. an emergency cart with the necessary medications and equipment to resuscitate an apneic and unconscious patient and to provide continuous support while that patient is being transported to another area (e.g., ambu-bag and mask, nasopharyngeal and oropharyngeal airways, tongue blades, laryngoscope, endotracheal tubes);
  12. equipment for establishing an emergency airway; and
  13. emergency back-up power sufficient to ensure patient protection.
- e. Recovery: Recovery from conscious sedation (sedation analgesia) should be monitored by a practitioner with current ACLS and/or, if appropriate, PALS or other profession-specific equivalent training. Each recovering patient should be evaluated by a qualified practitioner for proper anesthesia recovery using criteria appropriate for the level of anesthesia.

### 3. *Regional Anesthesia:*

- a. Required expertise and experience of practitioners:
  1. In order to competently administer regional anesthesia, the practitioner:
    - should be professionally qualified in delivering such an agent;
    - should be available and be able to competently and proficiently use necessary monitoring and emergency equipment;
    - should not simultaneously be involved in the surgical procedure; and
    - should adhere to all those health and safety measures described in Conscious Sedation (Sedation Analgesia) and Supplemented Local Anesthesia, Chapter G, paragraph 2 (p. 11-13).

2. The practice:

- should have available written protocols for patient risk assessment, recovery room and documented emergency procedures; and
- should convene, at least annually, in-service training on these policies and procedures.

b. Other personnel:

1. The monitoring personnel should monitor relevant physiologic variables and be available from the time of administration of the anesthetic until recovery is judged adequate by an appropriate practitioner or the care of the patient is transferred to personnel performing recovery care.
2. RNs with documented competence to administer regional anesthesia, and to assist in any support or resuscitation measures, as required, should have the anesthesia component of the medical, dental or podiatric procedure supervised by a practitioner qualified for such supervision who is physically present and available to immediately diagnose and treat the patient for anesthesia complications or emergencies. (See Anesthesia Services, Chapter G, paragraph 1a, p. 11, for the qualifications for supervision.)

c. Training for practitioners should include:

1. current ACLS training and/or, if appropriate, PALS or other profession-specific equivalent training; and
2. continuing education in keeping with professional standards for maintaining quality of practice regarding proper dosages, age-related management of toxicity or hypersensitivity to anesthetic agents and medications.

d. Equipment: Equipment recommended in paragraph 2 (conscious sedation) of this chapter is also applicable to regional anesthesia.

e. Recovery: Recovery from regional anesthesia should be monitored by a practitioner with current ACLS and/or, if appropriate, PALS or other profession-specific equivalent training. Each recovering patient should be evaluated by a qualified practitioner for proper anesthesia recovery using criteria appropriate for the level of anesthesia.

*4. General Anesthesia: Unconscious/Deep Sedation, General Anesthesia, Administered by a Practitioner in an Office Setting:*

a. Required expertise and experience of practitioners:

1. In order to competently administer anesthetics that induce unconscious/deep sedation or general anesthesia to the patient, the practitioner:
  - should be professionally qualified in delivering such an agent; dentists should have dental anesthesia certification for parenteral sedation and general anesthesia issued by SED;



- should be available and be able to competently and proficiently use necessary monitoring and emergency equipment;
  - should adhere to all those health and safety measures described in paragraph 2 (Conscious Sedation) of this chapter, and should not simultaneously be involved in the surgical procedure. However, an appropriately credentialed dentist may administer unconscious/deep sedation or general anesthesia to help a patient tolerate the administration of local anesthesia but should not initiate the surgical procedure until the patient has recovered from the unconscious/deep sedation/general anesthesia to a level of conscious sedation. Recovery from this anesthesia should be monitored by a qualified practitioner not simultaneously performing the surgery (see paragraph 4e {Recovery} in this chapter).
2. The practice:
- should have available written protocols for patient risk assessment, recovery room and emergency procedures; and
  - should convene, at least annually, an in-service training on these policies and procedures.
- b. Other Personnel: When RNs with appropriate training, experience and documented competency (at a minimum, such education, training and proficiency as determined by success on a relevant examination should be equivalent to that required for a nationally recognized CRNA certificate) administer unconscious/deep sedation and/or general anesthesia and/or monitor the patient, the anesthesia component of the medical or dental procedure should be supervised by a practitioner qualified for such supervision who is physically present and available to immediately diagnose and treat the patient for anesthesia complications or emergencies (see Anesthesia Services, Chapter G, paragraph 1a, p. 11, for the qualifications for supervision).
- c. Training for practitioners should include:
1. current ACLS and/or, if appropriate, PALS or other profession-specific equivalent training; and
  2. continuing education in keeping with professional standards for maintaining quality of practice regarding proper dosages and administration.
- d. Equipment: Equipment recommended in paragraph 2 (Conscious Sedation) of this chapter is also applicable to unconscious/deep sedation or general anesthesia. Practitioners should administer unconscious/deep sedation and general anesthesia in accordance with those general hospital and ambulatory surgery standards cited in DOH regulations (see Appendix IV, p. 28). In addition, the following equipment should be immediately available for use unless invalidated by the nature of the patient or the procedure (e.g., the absence of an anesthesia circuit):
1. an accepted method of identifying and preventing the interchangeability of gases, whenever gases are used;
  2. an end-tidal carbon dioxide monitor (capnograph);

3. an in-circuit oxygen analyzer designed to monitor the oxygen concentration within the breathing circuit by displaying the oxygen percent of the total inspiratory mixture;
4. a respirometer (volumeter) measuring exhaled tidal volume;
5. temperature monitor;
6. oxygen failure-protection devices (fail-safe system) which have the capacity to announce a reduction in oxygen pressure and, at lower levels of oxygen pressure, to discontinue other gases when the pressure of the supply of oxygen is reduced;
7. special equipment to manage a difficult airway;
8. medications and equipment to treat malignant hyperthermia when triggering agents are used;
9. alarm systems for high, low (subatmospheric) and minimum ventilatory pressures (disconnect) in the breathing circuit for each patient under general anesthesia; and
10. a gas evacuation system.

When inhalation anesthetics are administered, there should be:

11. a vaporizer exclusion (interlock) system which ensures that only one vaporizer and, therefore, only a single anesthetic agent can be actuated on any anesthesia machine at one time;
  12. pressure-compensated anesthesia vaporizers, designated to administer a constant nonpulsatile output, which should not be placed in the circuit downstream of the oxygen flush valve;
  13. flow meters and controllers which can accurately gauge concentration of oxygen relative to the anesthetic agent being administered and prevent oxygen mixtures of less than 21 percent from being administered; and
  14. a reliable and adequate system for scavenging waste anesthetic gases.
- e. Recovery: Recovery from general anesthesia or unconscious/deep sedation should be monitored by a practitioner with current ACLS and/or, if appropriate, PALS or other profession-specific equivalent training. Each recovering patient should be evaluated by a qualified practitioner for proper anesthesia recovery using criteria appropriate for the level of anesthesia.

**CHAPTER H****Environment of Care**

*1. General:* OBS practices should comply with the following guidelines commensurate with the size of the practice and the scope and complexity of services provided:

- a. have fire fighting equipment to control a limited fire;
- b. prohibit smoking within the office environment;
- c. have a physical plant adequate in size and design and containing items such as beds, stretchers, operating tables and wheelchairs as appropriate to its scope of services;
- d. have sufficient operating rooms, examination/treatment rooms and recovery rooms/areas appropriate to the level of anesthesia utilized and the complexity of the surgery, to meet patient needs;
- e. have suitable surgical lighting;
- f. have a source of emergency power for lighting, and surgical, anesthesia and monitoring equipment adequate to ensure patient protection if power fails;
- g. have illuminated signs with emergency power capability to light all exits;
- h. have available intravenous fluids, administration devices and monitoring and resuscitation equipment appropriate to the types of surgery/invasive procedures performed and anesthesia administered;
- i. provide adequate patient and family waiting areas and storage areas;
- j. maintain logs of calibration and servicing of all monitoring equipment; and
- k. comply with all applicable federal, state and local laws, codes and regulations pertaining to fire prevention, building construction and occupancy, accommodations for the disabled, occupational safety and health and disposal of medical waste and hazardous waste (see Appendix I, p. 21).

*2. Infection Control:* OBS practices should implement policies for infection control that promote an aseptic environment and minimize the potential for cross-contamination. The practice should:

- a. comply with generally accepted standards for infection control;
- b. train staff in infection control practices, which should address the appropriate cleaning, disinfection and sterilization of equipment, and in handling patient care items as well as the implementation of universal precautions;
- c. maintain a schedule of cleaning and disinfection and sterilization of equipment and patient care items as appropriate to prevent cross-contamination;
- d. properly clean and monitor for effectiveness equipment used to clean, disinfect and sterilize patient care items;
- e. provide protective clothing and equipment, as appropriate;

- f. identify and take steps to address significant problems in infection control, including all postoperative infections, as a key component of the practice's performance improvement program (see Office Administration, Chapter C, paragraph 2, p. 5); and
- g. assure that all operating room surfaces including ceiling, walls and floors are cleanable.

## **CHAPTER I**

### **Ancillary Services**

*1. General:* Whether on-site or contracted out, ancillary services such as laboratory, radiology, pathology and pharmaceutical services should be made available in accordance with the patients' needs and the types and volume of surgery performed. In addition to the service-specific requirements listed in paragraphs 2-4 of this chapter, all ancillary services should meet the following requirements:

- a. Services should be supervised by personnel qualified in the respective area. If supervised by the practitioner, he or she should be qualified to assume the professional, organizational and administrative responsibility for the quality of the service rendered.
- b. All ancillary services located in the practice must meet the standards issued by the Occupational Safety and Health Administration (OSHA) and promulgated under the Clinical Laboratory Improvement Act (CLIA) as well as any other applicable state and federal standards (see Appendix I, items C and D, p. 21-22).

*2. Pharmaceutical:*

- a. The practice should comply with DOH regulations for controlled substances and applicable provisions of the New York State Public Health Law and the State Education Law.
- b. Secure and confidential records including documentation relative to the prescription/administration of all medications should be maintained to ensure the control and safe dispensing of drugs.

*3. Laboratory and Pathology:* Practices should comply with federal regulations (see Appendix I, item D, p. 22). If a specimen is sent out, a New York State permitted laboratory or, if examined in the office, a CLIA-approved pathology laboratory should ensure that all such biopsy specimens and excised lesions are properly handled including appropriate fixation, processing, staining of slides, interpretation and issuance of an official report in a timely fashion. Pathology and laboratory services should include:

- a. procedures that are appropriate to the patient's medical condition and planned surgical/invasive procedure;
- b. appropriate quality controls including validation of test results through the use of standardized controls;
- c. assurance that stained slides are maintained for at least 10 years from the date of the examination, and specimen blocks for at least two years from the date of the examination (as required by federal regulations). For frozen tissue from microscopically controlled excision of tissue (Mohs' surgery), the laboratory should retain remnants of tissue specimens in a manner that assures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by a qualified individual.

- d. authenticated, dated reports of all laboratory examinations performed in the patients' health records; and
- e. procedures for obtaining, identifying, storing and transporting specimens.

4. *Diagnostic Imaging Services:*

- a. Diagnostic imaging services include but are not limited to radiography, fluoroscopy, CT, MRI, ultrasound and nuclear medicine.
  - 1. The practice should either provide or arrange for any and all diagnostic imaging services needed for the surgical/invasive procedure(s).
  - 2. Diagnostic imaging should be performed by qualified/certified staff and interpreted by a qualified practitioner within 24 hours.
  - 3. Complete patient records should be maintained in a readily accessible location.
- b. Facilities should be operated in such a manner as to ensure compliance with DOH regulations pertaining to ionizing radiation and should be registered/licensed and inspected by a DOH office or local Department of Health with jurisdiction. (This does not apply to facilities that use MRI equipment exclusively.)
- c. Only those facilities licensed by DOH pursuant to such DOH regulations may use radioactive materials.

## Appendix I

### Administrative Information Useful to the Practice

#### *A. Title 10 Department of Health Regulations*

Copies of the State Department of Health regulations referred to in these guidelines are available upon request. Contact: Office of Regulatory Reform, New York State Department of Health, 2415 Corning Tower, Empire State Plaza, Albany, NY 12237, 518/473-7488, fax 518/486-4834; e-mail: b0019b@health.state.ny.us for information; web site: [www.health.state.ny.us](http://www.health.state.ny.us).

#### *B. Title 8 State Education Department Regulations*

Copies of State Education Department regulations referred to in these guidelines are available upon request Contact: Office of Professional Responsibility in the Office of the Professions, State Education Department, Cultural Education Center, Albany, New York 12230, 518/486-1765, fax 518/474-3863; e-mail: OPOPR@MAIL.NYSED.GOV; web-site: [www.op.nysed.gov](http://www.op.nysed.gov).

#### *C. Occupational Safety and Health Administration (OSHA)*

The U.S. Department of Labor Occupational Safety and Health Administration is responsible for the enforcement of the health and safety guidelines set forth in the OSHA Act of 1970. Practices are subject to the OSHA Hazard Communication Standard of 1987 and the Bloodborne Pathogen Standard 29 CFR 1910.1030. Both standards have specific requirements and require written policy manuals and formal training regarding the standards. Other applicable OSHA standards include Access to Employee Exposure and Medical Records, and Personal Protective Equipment. For OSHA materials, contact the local office of the New York State Department of Labor, or call the Department of Labor Consultative Services Bureau at 518/457-2238; e-mail: [james.rush@ny-ce-albany.osha.gov](mailto:james.rush@ny-ce-albany.osha.gov). Highlights of these documents include:

1. Annual training is required regarding hazardous materials used in the practice, disposal of such materials and action to be taken if there are spills.
2. All hazardous chemical containers should be labeled. Labels should include brand name, chemical name, manufacturer's name and address and a hazard warning.
3. A material safety data sheet (MSDS) must be obtained for each hazardous chemical and kept in an MSDS file in a central location.
4. Containers for biohazard (infectious) waste must be marked with the international biohazard symbol (this includes sharps disposal). Containers should be puncture-resistant, waterproof and have a tight lid and be marked with a biohazard tag or label. Waste must be sorted into infectious and noninfectious waste and disposed of separately according to state and local laws.
5. A written fire policy must be maintained and portable fire extinguishers must be strategically located.
6. Bloodborne pathogen standards require that an employer provide for cleaning, laundry and/or disposal of personal protective equipment and clothing.

*D. Clinical Laboratory Improvement Amendments (CLIA) (CLIA '88)*

New York State Public Health Law (PHL) requires that sites examining material derived from the human body hold a clinical laboratory permit. Although practitioner office-based laboratories testing their own patients are exempt from the PHL requirement to hold a permit, federal CLIA '88 regulations require that every site that performs laboratory testing register with the federal program. CLIA '88 registration is handled by the Department of Health.

1. Practitioner office-based sites that perform testing must hold a valid CLIA certificate issued according to the complexity of testing performed.
2. Practitioner office-based laboratories performing tests other than the most simple tests (CLIA waived) are subject to comparable quality control, recordkeeping, personnel, inspection and proficiency testing requirements as hospital and freestanding clinical laboratories performing the same procedures.
3. Information on CLIA '88 requirements may be obtained by contacting: Physician Office Laboratory Evaluation Program, New York State Department of Health, Wadsworth Center, Empire State Plaza, P.O. Box 509, Albany, NY 12201-0509, 518-485-5352; e-mail: CLIA@health.state.ny.us

*E. Americans with Disabilities Act*

Copies may be obtained by contacting: Equal Employment Opportunity Commission, 1-800-669-4000 or web site: [www.eeoc.gov](http://www.eeoc.gov).

*F. National Fire Protection Association—NFPA Life Safety Code*

Copies may be obtained by contacting: National Fire Protection Association, One Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101, 617/770-4543.

*G. Codes of Ethical Business and Professional Behavior*

Available from:

American College of Surgeons  
55 East Erie Street  
Chicago, IL 60611-2797  
312-202-5000

American Society of Anesthesiologists  
520 North Northwest Highway  
Park Ridge, IL 60068-2573  
847-825-5586

American Medical Association  
515 North State Street  
Chicago, IL 60610  
1-800-634-6922 or 1-800-621-8335

Contact other specialty societies for specific information.



*H. Title 10 Definition of Certified Registered Nurse Anesthetist (CRNA)*

New York State Department of Health regulations Title 10 700.2(b)(22) define CRNA as:  
“a registered professional nurse licensed and currently registered with the New York State Education Department who:

1. has satisfactorily completed a prescribed course of study in a school of nurse anesthesia accredited by the Council on Accreditation of Nurse Anesthesia Education Programs/Schools or other accrediting body which the Commissioner of Health finds to be substantially equivalent;
2. has passed the national certifying examination given by the Council on Certification of Nurse Anesthetists or other certifying examination which the Commissioner of Health finds to be substantially equivalent; and
3. is currently certified by the Council on Certification of Nurse Anesthetists or by the Council on Recertification of Nurse Anesthetists or other accreditation body which the Commissioner of Health finds to be substantially equivalent.”

## **Appendix II**

### **Resource Documents Used in the Development of Clinical Guidelines for Office-based Surgery**

Following is a list of resource documents used by the Committee in its research and deliberations to assess the current practice of office-based surgery and to develop its recommendations for appropriate guidelines:

1. Legislation adopted by the State of California in 1997 (AB 595) regarding Surgical and Anesthesia Standards in an Office Setting.
2. Regulations adopted in 1998 by the New Jersey State Board of Medical Examiners.
3. Legislation adopted by the State of Florida (Chapter 59 R-9.009 Standard of Care for Office Surgery) and proposed amendments to such legislation.
4. American Society of Anesthesiologists/Society for Ambulatory Anesthesia comments and questions regarding the New Jersey regulations.
5. American College of Surgeons Guidelines for Optimal Office-based Surgery (October 1996).
6. American Society of Anesthesiologists Practice Parameters for Sedation and Analgesia by Non-Anesthesiologists.
7. Joint Commission on the Accreditation of Healthcare Organizations Standards for Ambulatory Care (1998).
8. Crosswalk between the American College of Surgeons' Guidelines for Optimal Office-based Surgery and the Joint Commission's Ambulatory Care Standards (1998).
9. American Society of Anesthesiologists/Society for Ambulatory Anesthesia Response to the ACS/JCAHO Crosswalk Document.
10. New York State Education Department documents related to dentistry:
  - a. Memorandum on Conscious Sedation and General Anesthesia in Ambulatory Settings (June 1996).
  - b. Regulation section 61.10 General Anesthesia and Parenteral Sedation.
  - c. Application Procedures for Dental Anesthesia Certification.
11. New York State Department of Health Regulations:
  - a. 405.12 Hospital Based Surgical Services,
  - b. 405.13 Hospital Based Anesthesia Services,
  - c. 405.20 Hospital Based Outpatient Services,
  - d. 715 Standards for Construction for Ambulatory Surgery Centers
  - e. 755 Freestanding Ambulatory Surgery Services.

12. American Academy of Dermatology Guidelines for Care in Office Surgical Facilities (reprinted from the *Journal of the American Academy of Dermatology*, May 1992).
13. American Medical Accreditation Program Environment of Care Survey.
14. *American Association of Oral and Maxillofacial Surgeons Parameters of Care for Oral and Maxillofacial Surgery*, Volume 53, Number 9 Supplement 5, September 1998
15. New York State Podiatric Medical Association Guidelines for Office-based Surgery (1998).
16. American Association of Nurse Anesthetists document “Providing Anesthesia into the Next Century.”
17. Documents from the American Association for Accreditation of Ambulatory Surgery Facilities, Inc.
18. Accreditation Association for Ambulatory Health Care, Inc. Accreditation *Handbook for Ambulatory Health Care* (1998).

## **Appendix III**

### **Model Office-based Surgery Patients' Bill of Rights**

A Bill of Rights should include the following:

1. The patient has the right to high-quality care delivered in a safe, timely, efficient and cost-effective manner and the right to be assured that the expected results can be reasonably anticipated.
2. The patient has the right to dignity, respect and consideration of legitimate concerns.
3. The patient has the right to privacy and confidentiality.
4. Patients are involved in all aspects of care. Informed consent, following a discussion of risks, benefits and alternatives, should be obtained. The patient has the right to information about the current diagnosis, treatment and prognosis. If it is not advisable to give such information to the patient for health reasons, the information should be available to a person designated by the patient or a legally authorized person.
5. The patient has the right to be advised of all reasonable options/alternatives for care and treatment and the potential advantages/disadvantages of each. Included in this should be a discussion of the advantages/disadvantages and alternatives to having the procedure performed in the office.
6. The patient has the right to refuse any diagnostic procedure or treatment, and to be advised of the likely medical consequences of such refusal.
7. The patient has the right to education to address his or her needs. The educational process should consider the patient's values, abilities, readiness to learn and patient and family responsibilities in the care process.
8. The patient has the right to know who will be delivering the care and the qualifications of such individuals. In the case of student personnel (including residents/fellow), the patient has the right to know the extent to which the student personnel will be involved.
9. The patient has the right to change the practitioner if other qualified practitioners are available.
10. The patient has the right to inspect and obtain a copy of his or her medical records. In addition, the patient has the right to expect a reasonable and timely transfer of information from one practitioner to another when required. Charges for copies of medical records should not exceed the charges provided for by Section 17 of the Public Health Law.
11. The patient has the right to request and receive information concerning the bill for services regardless of the source of payment.

12. The patient has the right to request and receive information about alternate sources of appropriate care.
13. The patient has the right to know about the expectations of the office-based practice with regard to his or her behavior and the consequences of failure to comply with these expectations.

## **Appendix IV**

### **Department of Health Regulations**

Effective Date: 01/01/89 NYCRR Title 10 Section 405.13—Anesthesia services

405.13 Anesthesia services. If anesthesia services are provided within a hospital, the hospital shall develop, implement and keep current effective written policies and procedures regarding staff privileges, the administration of anesthetics, the maintenance of safety controls and the integration of such services with other related services of the hospital to protect the health and safety of the patients in accordance with generally accepted standards of medical practice and patient care.

- (a) Organization and direction. Anesthesia services shall be directed by a physician who has responsibility for the clinical aspects of organization and delivery of all anesthesia services provided by the hospital. That physician or another individual qualified by education and experience shall direct administrative aspects of the service.
- (1) The director shall be responsible, in conjunction with the medical staff, for recommending to the governing body privileges to those persons qualified to administer anesthetics, including the procedures each person is qualified to perform and the levels of required supervision as appropriate. Anesthesia shall be administered in accordance with their credentials and privileges by the following:
  - (i) anesthesiologists;
  - (ii) physicians granted anesthesia privileges;
  - (iii) dentists, oral surgeons, or podiatrists who are qualified to administer anesthesia under State law;
  - (iv) certified registered nurse anesthetists (CRNA's) under the supervision of an anesthesiologist who is immediately available as needed or under the supervision of the operating physician who has been found qualified by the governing body and the medical staff to supervise the administration of anesthetics and who has accepted responsibility for the supervision of the CRNA; or
  - (v) a student enrolled in a school of nurse anesthesia accredited by the Council on Accreditation of Nurse Anesthesia Educational Programs may administer anesthesia as related to such course of study under the direct personal supervision of a certified registered nurse anesthetist or an anesthesiologist.
- (2) Anesthesia service policies shall clearly outline requirements for orientation and continuing education programs for all staff, and staff compliance with such requirements shall be considered at the time of reappointment or performance evaluation. Such training and continuing education programs shall be established that are relevant to care provided but must, at a minimum, include instruction in safety precautions, equipment usage and inspections, infection control requirements and any patients' rights requirements pertaining to surgical/anesthesia consents.

- (3) The director shall, in conjunction with the medical staff, monitor the quality and appropriateness of anesthesia related patient care and ensure that identified problems are reported to the quality assurance committee and are resolved.
- (b) Operation and service delivery. Policies governing anesthesia services shall be designed to ensure the achievement and maintenance of generally accepted standards of medical practice and patient care.
- (1) All anesthesia machines shall be numbered and reports of all equipment inspections and routine maintenance shall be included in the anesthesia service records. Policies and procedures shall be developed and implemented regarding notification of equipment disorders/malfunctions to the director, to the manufacturer and, in accordance with section 405.8 of this Part, to the department.
- (2) Written policies regarding anesthesia procedures shall be developed and implemented which shall clearly delineate pre-anesthesia and post-anesthesia responsibilities. These policies shall include, but not be limited to, the following elements:
  - (i) Pre-anesthesia physical evaluations shall be performed by an individual qualified to administer anesthesia and recorded within 48 hours, prior to surgery.
  - (ii) Routine checks shall be conducted by the anesthetist prior to every administration of anesthesia to ensure the readiness, availability, cleanliness, sterility when required, and working condition of all equipment used in the administration of anesthetic agents.
  - (iii) All anesthesia care shall be provided in accordance with accepted standards of practice and shall ensure the safety of the patient during the administration, conduct of and emergence from anesthesia. The following continuous monitoring is required during the administration of general and regional anesthetics. Such continuous monitoring is not required during the administration of anesthetics administered for analgesia or during the administration of local anesthetics unless medically indicated.
    - (a) An anesthetist shall be continuously present in the operating room throughout the administration and the conduct of all general anesthetics, regional anesthetics, and monitored anesthesia care. If there is a documented hazard to the anesthetist which prevents the anesthetist from being continuously present in the operating room, provision must be made for monitoring the patient.
    - (b) All patients must be attended by the anesthetist during the emergence from anesthesia until they are under the care of qualified post-anesthesia care staff or longer as necessary to meet the patient's needs.
    - (c) During all anesthetics, the heart sounds and breathing sounds of all patients shall be monitored through the use of a precordial or esophageal stethoscope. Such equipment or superior equipment shall be obtained and utilized by the hospital.

- (d) During the administration and conduct of all anesthesia the patient's oxygenation shall be continuously monitored to ensure adequate oxygen concentration in the inspired gas and the blood through the use of a pulse oximeter or superior equipment. During every administration of general anesthesia using an anesthesia machine, the concentration of oxygen in the patient's breathing system shall be measured by an oxygen analyzer with a low oxygen concentration limit alarm.
- (e) All patients' ventilation shall be continuously monitored during the conduct of anesthesia. During regional anesthesia, monitored anesthesia care and general anesthesia with a mask, the adequacy of ventilation shall be evaluated through the continual observation of the patient's qualitative clinical signs. For every patient receiving general anesthesia with an endotracheal tube, the qualitative carbon dioxide content of expired gases shall be monitored through the use of endtidal carbon dioxide analysis or superior technology. In all cases where ventilation is controlled by a mechanical ventilator, there shall be in continuous use an alarm that is capable of detecting disconnection of any components of the breathing system.
- (f) The patient's circulatory functions shall be continuously monitored during all anesthetics. This monitoring shall include the continuous display of the patient's electrocardiogram, from the beginning of anesthesia until preparation to leave the anesthetizing location, and the evaluation of the patient's blood pressure and heart rate at least every five minutes.
- (g) During every administration of anesthesia, there shall be immediately available a means to continuously measure the patient's temperature.
- (iv) Intraoperative anesthesia records shall document all pertinent events that occur during the induction, maintenance, and emergence from anesthesia. These pertinent events shall include, but not be limited to, the following: intraoperative abnormalities or complications, blood pressure, pulse, dosage and duration of all anesthetic agents, dosage and duration of other drugs and intravenous fluids, and the administration of blood and blood components. The record shall also document the general condition of the patient.
- (v) With respect to inpatients a post-anesthetic follow-up evaluation and report by the individual who administered the anesthesia or by an individual qualified to administer anesthesia shall be written not less than three or more than 48 hours after surgery and shall note the presence or absence of anesthesia related abnormalities or complications, and shall evaluate the patient for proper anesthesia recovery and shall document the general condition of the patient.
- (vi) With respect to outpatients, a post-anesthesia evaluation for proper anesthesia recovery performed in accordance with policies and procedures approved by the medical staff shall be documented for each patient prior to hospital discharge.



3. Safety precautions shall be clearly identified in written policies and procedures specific to the department and include, but not be limited to:

- (i) safety regulations posted;
- (ii) routine inspection and maintenance of equipment;
- (iii) use and maintenance of shockproof equipment;
- (iv) proper grounding; and
- (v) infection control.

Effective Date: NYCRR Title 10 Section 755.4—Anesthesia services

755.4 Anesthesia services. The operator shall ensure that:

- (a) an anesthesiologist, licensed by and currently registered with the New York State Education Department, and who meets the definition of a qualified specialist, is responsible for the anesthesia services and may fulfill the requirement for medical director;
- (b) administration of anesthesia is in accordance with current standards of professional practice;
- (c) anesthesia is administered by only a qualified anesthesiologist, or a physician or dentist qualified to administer anesthesia, or a certified registered nurse anesthetist;
- (d) when nonphysicians administer anesthesia, the anesthetist must be under the direct personal supervision of a qualified physician, who may be the operating surgeon;
- (e) the person administering the anesthesia, other than local anesthesia, is not the operating surgeon; and
- (f) a physician examines each patient immediately prior to surgery to evaluate the risk to anesthesia and the procedure to be performed.



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